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Advancing Quality Transformation

Best practices for generics manufacturers and CDMOs.

For decades, costly regulatory issues bore witness to pharma's reactive approach to quality.[1] Billion-dollar consent decrees,[2] caused by fundamental quality failures, drove some manufacturers out of business, while regulators continued to find fault with practices ranging from inadequate CAPA and root-cause analysis to insufficient contract partner oversight.

Industry initiatives such as 21st-century GMPs,[3] Pharmaceutical Process Analytical Technology and Quality by Design,[4] and ICH Q10,[5] exposed pharma to quality concepts used in other industries, such as process capability, statistical process control, risk assessment, and other tools designed to reduce variability. Until this point, many pharma companies had focused on compliance documentation and finished product testing, and invested in better, more modern approaches only after a product recall or Warning Letter.

As more companies modernize their approach to quality management, regulators are emphasizing the need for companies to bring real-world quality metrics into their day-to-day operations and find ways to build a culture of quality[6] within their organizations. In response, more pharmaceutical manufacturers are reducing variability in their processes and taking a proactive approach to quality as an enabler of operational excellence[7] rather than a cost center. In the process, they are saving millions of dollars per year.

GENERICS AND CDMOS IMPROVE QUALITY SYSTEMS, DESPITE TIGHT MARGINS

As competitive pressures increase and manufacturing becomes more complex, the ability to deliver consistent product quality is now a crucial business differentiator. Consistent, proactive quality management suggests that a company uses data-driven techniques for better control over manufacturing processes, whether they occur within its walls or those of contract development and manufacturing organization (CDMO). But achieving this control can be challenging for generic pharmaceutical manufacturers and CDMOs, which operate on much tighter budgets and shorter timeframes than name-brand pharma companies.

To redefine their quality programs' goals, more life sciences companies are investing in digital tools[8] and replacing old enterprise-based content and data management systems with cloud-based applications to improve operational efficiency. A 2021 survey of C-level and senior quality executives at generic pharmaceuticals and biosimilars manufacturers, CDMOs, and name-brand drug companies, provides insights into how cloud-based applications enable improved quality operations. Instead of integrating traditional point solutions, the survey found, these companies are leveraging the cloud to support end-to-end quality functions on a single platform (*Figure 1*).

Respondents agreed that older quality systems were more difficult to scale and made it more challenging to bring suppliers and other external partners into their processes than cloud-based systems. "Paper creates an additional barrier to change, where the right electronic systems improve efficiency, supporting improved quality and continuous improvements in manufacturing and distribution," said Melanie Cerullo, senior vice president of quality and regulatory management at Arranta Bio, a CDMO specializing in work with developers of microbiome-focused therapies.

IMPROVING COLLABORATION

With cloud-based systems, "I don't have to be on-site to dig through a filing cabinet to see a batch record revision history. It's all there, and I can extract what I need or provide a snippet and direct somebody on the floor to keep the business going," said Roxanne Hill, quality systems manager for Upsher-Smith Laboratories, a generic pharmaceuticals company that also manufactures name-brand migraine and anti-convulsive treatments.

For progressive CDMOs and generics manufacturers, the cloud offers a way to aggregate data to gain insights into the root cause of quality issues such as deviations and out-of-specification (OOS) events. It also improves the management of quality metrics and key performance indicators, particularly when used with IoT-enabled devices. These capabilities, along with assured data integrity, are crucial to reducing quality risks, according to Sérgio Paulo Simões, founder and board member of Bluepharma, a generic pharmaceuticals company in Portugal.

DATA AGGREGATION AND VISIBILITY

Greater data visibility is another major benefit of cloud-based systems, the executives agreed. "With the cloud, when we review quality documents or batch records, it's easy to search for a specification and compare it to a certificate of analysis or certificate of compliance to ensure that the data match," said James Horger, vice president of quality at the generic pharmaceuticals and biosimilars manufacturer, Sagent Pharmaceuticals.

This enhanced visibility also facilitates real-time data reporting. "We can now see and extract data in real-time. If a deviation occurs on the manufacturing floor, we can determine whether it's a repeat deviation or something brand new. We couldn't do that with traditional IT systems using paper-based processes," said Hill.

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BEST PRACTICES TO ADVANCE QUALITY TRANSFORMATION

Adopters of cloud-based quality applications shared the following best practices.

Address the fear of losing control

In moving to the cloud, a company doesn't lose control of its data. Instead, stakeholders must decide who can access the information in the various applications and what they can do with it once access is granted. It is vitally important to take the time to understand the appropriate level of security required for both internal and external users in cloud applications.

Figure 1. End-to-end functions on a single platform.

Don't bring legacy baggage to the cloud

Start with a clean slate to avoid developing requirements based on what is needed for legacy quality systems. Develop requirements that leverage native cloud quality system capabilities as much as possible and consider whether those requirements allow external parties to access the application securely. Finally, take advantage of the cloud's out-of-the-box functionality and built-in best practices.

Assemble cross-functional teams to understand processes and requirements

Cross-functional meetings with subject matter experts (SMEs) across the organization are vital to ensuring that requirements are documented, rationalized, and agreed upon.

Spend the necessary time upfront to understand what the system needs to be able to do on the back end. Identify the reports that must run, the data that needs to be collected, and how it will be sliced and diced, because that will determine which features get turned on in the configuration. Finally, consider how staff will use and access the information to ensure that the proper parameters are built-in.

Don't force paper processes into an electronic system

Don't simply force existing paper processes into a new electronic system; use the implementation plan as an opportunity to refine processes. Ensure that the right people are in the room, each offering a different perspective when the company decides how an individual record will look, how a workflow will actually work, or how a document will be used downstream.

Beware of cloud imitators

Beware of hosted versions of legacy solutions advertised and offered as cloud solutions. Verify that end-to-end functionality is available within a single quality platform and select a platform that will scale to support business growth and quality improvements.

Executives from generics and CDMOs who adopted end-to-end quality systems in the cloud emphasized the savings they achieved by streamlining processes, data, and content in one system. They saw gains in business process efficiencies with tangible payback and improved user experience.

For any company moving quality data and documentation from an enterprise IT platform to the cloud, success depends on culture change. This applies to system selection and implementation and computer system validation practices. As the industry takes a risk-based approach to validation, companies that work in the cloud benefit by starting with pre-validated software and leveraging vendor-delivered IQ/OQ and other data.

Evidence suggests that end-to-end cloud-based processes are already helping generic pharmaceutical companies, CDMOs, and other life sciences companies improve quality operations[9] and make quality more of a strategic business driver as they grow. **CP**

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